

September 16, 2021

RECEIVED

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Anabel Renteria
Initiative Coordinator
Office of the Attorney General
1300 I Street, 17th Floor
Sacramento, CA 95814-2919

INITIATIVE COORDINATOR
ATTORNEY GENERAL'S OFFICE

Re: Request for Circulating Title and Summary
"California Pandemic Early Detection and Prevention Act"

Dear Ms. Renteria:

We serve as counsel for the proponents of the enclosed proposed statewide initiative, the "California Pandemic Early Detection and Prevention Act." The proponents of the proposed initiative are:

- Max Henderson
- Anna Maybach

On their behalf, I am enclosing the following documents:

- Proponents' Request for Circulating Title and Summary
- Proponent certifications pursuant to Elections Code section 9001(b)
- Proponent certifications pursuant to Elections Code section 9608
- A check in the amount of \$2,000.00
- Text of the "California Pandemic Early Detection and Prevention Act" Initiative

All inquiries or correspondence relative to this proposed initiative, should be directed to:

George M. Yin
Kaufman Legal Group
777 S. Figueroa Street, Suite 4050
Los Angeles, CA 90017
Tel: (213) 452-6565

September 16, 2021

Anabel Renteria
Initiative Coordinator
Office of the Attorney General
P.O. Box 944255
Sacramento, CA 94244-2550

Re: Request for Title and Summary for Proposed Initiative

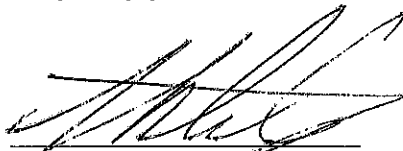
Dear Ms. Renteria:

Pursuant to Article II, Section 10(d) of the California Constitution, I submit the attached proposed Initiative, entitled "California Pandemic Early Detection and Prevention Act" to your office and request that your office prepare a title and summary. Included with this submission is the required proponent certifications pursuant to sections 9001 and 9608 of the California Elections Code, along with a check for \$2,000.00.

All inquiries or correspondence relative to this initiative should be directed to George Yin at Kaufman Legal Group, APC, 777 S. Figueroa St., Suite 4050, Sacramento, CA, (213) 452-6576.

Thank you for your assistance.

Very truly yours,



Max Henderson
Proponent

Anna Maybach
Proponent

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Office of the Attorney General
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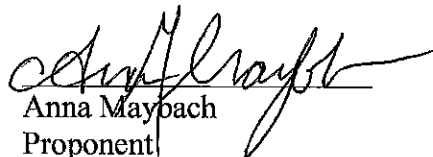
Pursuant to Article II, Section 10(d) of the California Constitution, I submit the attached proposed Initiative, entitled "California Pandemic Early Detection and Prevention Act" to your office and request that your office prepare a title and summary. Included with this submission is the required proponent certifications pursuant to sections 9001 and 9608 of the California Elections Code, along with a check for \$2,000.00.

All inquiries or correspondence relative to this initiative should be directed to George Yin at Kaufman Legal Group, APC, 777 S. Figueroa St., Suite 4050, Sacramento, CA, (213) 452-6576.

Thank you for your assistance.

Very truly yours,

Max Henderson
Proponent


Anna Maybach
Proponent

PROPOSED LAW

CALIFORNIA PANDEMIC EARLY DETECTION AND PREVENTION INITIATIVE

SECTION 1. Title

This measure shall be known as the “California Pandemic Early Detection and Prevention Act.”

SECTION 2. Findings and Declarations.

The people of California find and declare the following:

(a) The COVID-19 pandemic produced massive health, economic, and social damage to the people, businesses, schools, and state of California, costing over 65,000 lives, 1.6 million jobs, and reducing California’s economic output by at least \$200 billion dollars. Worse, if we do not prepare now, scientists believe the next pandemic could be many times more costly, in both dollars and lives.

(b) The COVID-19 pandemic affected everyone in California and exacerbated existing inequities, disproportionately impacting low-income and underserved communities, communities of color, the elderly, frontline workers, teachers, and students. Californians, especially these communities, cannot afford more devastating pandemics.

(c) As California is economically and culturally diverse, highly populated, and globally connected, it is at increased risk of future pandemics, and will likely be one of the first places in the United States to be impacted by a new pandemic, as it was during COVID-19.

(d) Early detection and containment of COVID-19 would have saved lives and money, reduced suffering, prevented lockdowns, and allowed schools and businesses to remain open. Unfortunately, the federal government is not providing adequate funding for the urgent work needed to protect us from the next pandemic.

(e) The California Pandemic Early Detection and Prevention Act will close this gap by investing in the technology needed to create an early-warning system to detect, prevent, and defeat biological threats before they become pandemics. By catching new disease outbreaks early, Californians can more rapidly develop effective countermeasures, including vaccines and therapeutics, and contain outbreaks before they cause grave suffering and costly lockdowns. If this effort helps prevent a future pandemic of COVID-19 scale or greater, this investment will pay for itself many times over.

(f) Further, this technology will have far reaching health benefits, including personalized medicine, better clinical diagnostics, and novel treatments for disease. These benefits will improve the health of all Californians.

(g) By enacting this initiative, California will become a global leader in this exciting new area of technology and will serve as a model for the nation and the world while creating thousands of

new, well-paid jobs, generating millions of dollars in new tax revenues, and drawing talent and private investment into the state.

(h) While many Californians suffered economically due to the COVID-19 pandemic, many of the wealthiest Californians prospered during the same period. This initiative, therefore, will ask only the wealthiest Californians to pay slightly more in taxes – only on their income over \$5 million per year – to help avert the suffering caused to all Californians by future pandemics. The vast majority of Californians will not be impacted by any new tax.

(i) This use of science and technology to prevent future pandemics will be conducted with the utmost respect and accountability for Californians' tax dollars, be led by science, and have world-class ethics, audits, oversight, and conflict of interest protections. To ensure urgency, focus, and accountability, this effort will be limited to raising funds for a 10-year period.

SECTION 3. Purpose and Intent

It is the intent of the people of California in enacting this measure to:

(a) Detect, prevent, and mitigate future pandemics through early detection and identification of disease outbreaks, including those previously unknown to science, to protect the health and financial well-being of all Californians equitably and reduce the degree to which pandemics exacerbate human suffering and inequality.

(b) Ensure the creation of a flexible, scalable, and cost-effective system for detecting harmful pathogens that can be deployed in hospitals, schools, public spaces, and any other environment where its use would help safeguard the health and well-being of Californians.

(c) Create and fund an independently governed public grantmaking organization, called the California Pandemic Early Detection and Prevention Institute ("CPDI" or "institute"), to accelerate the development of pathogen-agnostic metagenomic sequencing, which will be at the core of any pandemic early-warning system, and any technologies, procedures, and infrastructure needed to deploy it, with a particular emphasis on translating research into practical technologies that can be deployed at scale.

(d) Facilitate close cooperation between government, stakeholders, and the institute, and provide decision makers, such as the California Department of Public Health, the tools they need to prevent pandemics.

(e) Ensure grants are awarded responsibly by screening all proposals for potential harm, including biosecurity and biosafety risks, infringements upon personal privacy or liberties, or other ethical concerns.

(f) Set an example to the nation and the world and bring economic benefits to California for being a first mover in this emerging field.

(g) Achieve these goals with world-class institutional governance and transparency, including external auditing, independent oversight, and conflict-of-interest prevention provisions.

SECTION 4. Article XXXVI is added to the California Constitution, to read:

Article XXXVI. Pandemic Research and Preparedness

SEC. 1. There is hereby established the California Pandemic Early Detection and Prevention Institute.

SEC 2. The Institute shall have the following purposes:

- (a) To award grants to accelerate the development of pathogen-agnostic metagenomic sequencing for detecting and preventing pandemics.*
- (b) To support all stages of the process of implementing a pathogen-agnostic metagenomic-sequencing-based pandemic detection system, from research through successful real-world use.*
- (c) Make grants responsibly by screening all proposals to achieve public benefit and to hold them to high standards of ethics, privacy, and security.*
- (d) Interface with California public health authorities in these practical applications and real-world deployments, so that they can act quickly to mitigate or prevent future pandemics.*

SEC. 3. Funds authorized for, or made available to the institute, shall be continuously appropriated without regard to fiscal year, and used only for the purposes provided in this article, and shall not be subject to appropriation or transfer by the Legislature or the Governor for any other purpose.

SEC. 4. Notwithstanding any other provision of this Constitution or any law, the institute, which is established in state government, may utilize tax revenue, and receive real and personal property, including, but not limited to, gifts, royalties, interest, grants, and contributions to fund its operations and grant awards.

SEC. 5. Notwithstanding any other provision of this Constitution, including Article VII, or any law, the institute and its employees are exempt from civil service.

SECTION 5. Division 121 (commencing with Section 152000) is added to the Health and Safety Code, to read:

*DIVISION 121
Pandemic Early Detection and Prevention Research Funding Act*

*CHAPTER 1
General Provisions*

152000. Creation of Institute.

This division implements Article XXXVI of the California Constitution, which established the California Pandemic Early Detection and Prevention Institute ("CPDI" or "institute").

152005. Independent Scientific Governing Board.

There is hereby created the Independent Scientific Governing Board, hereinafter ISGB, which shall govern the institute and is hereby vested with full power, authority, and jurisdiction over the institute.

(a) Membership and Appointment

The ISGB shall have 7 members.

(1) Six board member(s) shall be appointed as follows:

(A) To ensure close cooperation between the California Department of Public Health and the institute, the current California Department of Public Health Center for Infectious Diseases Deputy Director, or equivalent official, shall serve as one member. If the aforementioned Deputy Director position is vacant, the Director of the California Department of Public Health will serve as an ISGB member, until the role is filled.

(B) The Governor shall appoint one member who is a metagenomic sequencing expert with the following qualifications, and who shall serve an initial 6-year term:

(i) Demonstrated record of, and expertise in, developing methods for pathogen discovery or clinical diagnostics using metagenomic sequencing and metagenomic software tools, including practical experience implementing such technologies in either a clinical or epidemiological setting.

(ii) Demonstrated history, within the last 5 years of leading an institution with a yearly research or scientific grant-making budget exceeding fifty million dollars (\$50,000,000).

(iii) Holds an appointment at a university located in California as a professor in the life sciences, engineering, or medicine.

(C) The Governor shall appoint one member who is a medical doctor and infectious disease expert with the following qualifications, and who shall serve an initial 6-year term:

(i) Demonstrated record as an infectious disease epidemiologist, with expertise in infectious disease transmission reduction.

(ii) Holds an appointment at a university located in California as a professor in medicine or infectious disease.

(iii) Holds a Doctor of Medicine, or equivalent degree, from a medical school recognized by the State of California.

(D) The Governor shall appoint one member with expertise in data science, computer science, or bioinformatics with the following qualifications, and who shall serve an initial 5-year term:

(i) Demonstrated record using mathematical models, data science, genomics, computational biology, or electronic medical records to prevent, detect, model, or contain diseases.

(ii) Experience as an executive leading senior data scientist, bioinformatician or genomic epidemiologist.

(E) The Governor shall appoint one member who is an engineering expert with the following qualifications, and who shall serve an initial 5-year term:

(i) Experience as a founder, executive, or research director of a technology or life sciences company that has successfully brought new technology to market and achieved over one billion dollars (\$1,000,000,000) in annual sales.

(ii) Demonstrated expertise in solid-state physics, materials science, semiconductor electronics, microfluidics, or nanotechnology.

(F) The Governor shall appoint one member who is a technology commercialization expert with the following qualifications, and who shall serve an initial 4-year term:

(i) At least 10 years' experience as a founder, managing director, or general partner of an organization investing in technology or healthcare, with over 1 billion dollars (\$1,000,000,000) in assets under management.

(ii) Educational background in the biological sciences, biochemistry, physical chemistry, physics, or engineering.

(iii) Experience as a founder of a technology or life sciences company is preferred.

(2) The seventh board member will be the chief executive officer, who shall be selected and hired with approval by the six appointed board members, as described in section 152010. The chief executive officer's initial term shall be 10 years.

(3) All appointments shall be made within 30 days of the effective date of this act. In the event that any of the appointments are not completed within this timeframe, the ISGB shall proceed to operate with appointments that are in place, provided that at least 4 appointments have been made.

(b) Terms and Removal

(1) Subsequent to their initial terms, ISGB members shall serve six-year terms, except for the chief executive officer, who shall serve a 10-year term, and the California Department of Public Health Center for Infectious Diseases Deputy Director, who shall serve as provided in subdivision (a) and shall not be subject to term limits; other ISGB members and the chief executive officer may serve a maximum of two terms, unless earlier removed pursuant to paragraph (5).

(2) If a vacancy of an appointed member occurs within a term, the appointing authority shall appoint a replacement member pursuant to subdivision (a)(1) within 40 days.

(3) If a vacancy occurs in the chief executive officer position, the ISGB shall elect an interim chief executive officer from among the remaining ISGB members within 14-days, and hire a new chief executive officer within 120 days.

(4) When the initial term of an appointed ISGB member expires, the appointing authority shall appoint a member within 40 days. ISGB members shall continue to serve until their replacements are appointed.

(5) The ISGB may, by an affirmative vote of 5 ISGB members, remove an ISGB member for good cause, except the chief executive officer. Upon such removal, the appointing authority shall appoint a new ISGB member as set forth in paragraph (2). The ISGB may, by an affirmative vote of 5 ISGB members, remove the chief executive officer for good cause. Upon such removal, the ISGB shall hire a replacement as set forth in paragraph (3).

(c) Vote of Quorum

Any actions taken by the ISGB shall require the approval of 4 or more members. This shall be the case even if less than 7 members of the ISGB have assumed office or are otherwise absent from a meeting of the ISGB.

(d) Functions

The ISGB shall perform the following functions:

(1) *Provide oversight for the operations of the institute, except that ISGB members, with the exception of the chief executive officer, shall have no direct involvement with, nor shall attempt to influence, any specific grant award decision.*

(2) *Provide oversight and evaluation of the institute's financial performance, grantee progress towards performance of the terms of grant awards, and institute standards, ethics, and legal compliance.*

(3) *Elect and evaluate the performance of the chief executive officer, including removing and replacing the chief executive officer, at the ISGB's discretion.*

(4) *Advise the chief executive officer on, and ratify by vote:*

(A) *Annual and long-term strategic plans for the institute, including Key Funding Areas (as defined in subdivision (d) of Section 152030) and research priorities, operational plans, and financial plans.*

(B) *Annual budget proposals.*

(C) *Hiring decisions for committee members.*

(D) *The institute's grant review procedure.*

(E) *Intellectual property agreement standards for grant awards that closely align with the Bayh-Dole Act (35 U.S.C. § 200–212).*

(5) *Represent the institute in external affairs.*

(6) *Ensure the completion of an annual financial and management audit of the institute's operations.*

(7) *Issue public reports on the activities of the institute.*

(8) *Assist with continuity planning and recruitment of ISGB members, committee members, and key institute employees.*

(9) *Employ legal counsel, including outside counsel from the private sector, at the ISGB's discretion. Upon request of the ISGB, the Attorney General shall provide legal advice and representation without charge to the ISGB or the institute.*

(10) *Notwithstanding Section 11005 of the Government Code, the ISGB may accept additional revenue and real and personal property, including, but not limited to, gifts, royalties, interest, grants, contributions, and appropriations that shall be used to supplement annual research grant funding and the operations of the institute.*

(11) *Perform all other acts necessary or appropriate in the exercise of its power, authority, and jurisdiction over the institute.*

(12) *Delegate authority and responsibility to the chief executive officer as necessary to achieve the ends of the institute.*

(13) *Generally, adopt, amend, and rescind policies, rules, and regulations to carry out the purposes and provisions of this chapter, and to govern the procedures of the institute. Except as provided in paragraph (14) of this subdivision, these policies, rules, and regulations shall be adopted in accordance with the Administrative Procedure Act (Government Code, Title 2, Division 3, Part 1, Chapter 3.5, Sections 11340 et seq.).*

(14) *Notwithstanding the Administrative Procedure Act (APA), and in order to facilitate the immediate commencement of research covered by this chapter, the ISGB may adopt interim policies, rules, and regulations without compliance with the procedures set forth in the APA. The interim regulations shall remain in effect for 270 days unless earlier superseded by regulations adopted pursuant to the APA.*

152010. Chief Executive Officer.

(a) Selection

(1) *A chief executive officer of the institute shall be hired by the ISGB within 120 days after the ISGB begins to operate.*

(b) Qualifications

The chief executive officer shall meet the following mandatory criteria:

(1) *Experience as an executive officer leading a large-scale operation in science or technology with an annual budget in excess of ten million dollars (\$10,000,000), including setting strategic direction, hiring, and overseeing an organization managing partnerships, science/engineering, and operations.*

(2) *Demonstrated success leading or funding the development of new technology in one of the following settings:*

(A) *corporate research and development at a technology or life science company;*

(B) *governmental grant-making organizations focused on science and technology, health, biomedical research, or infectious disease;*

(C) *non-profit grant making organizations focused on science and technology, health, biomedical research, or infectious disease.*

(3) *Additional preferred criteria for consideration:*

(A) *Experience as a founder or executive of a company or non-profit in the technology or life sciences sectors.*

(B) *Experience liaising with government organizations, such as state and local public health departments.*

(C) *A science, engineering, or mathematical educational background.*

(D) *An advanced degree such as a Ph.D. or Doctor of Medicine (M.D.).*

(E) *Experience in the area of biosecurity or infectious disease.*

(c) *Role and Functions*

The chief executive officer of the institute shall:

(1) *Serve as the chief executive of the institute, and manage daily operations of the institute, including but not limited to, administration, human resources, accounting, and public relations.*

(2) *Be a full-time employee of the institute and shall serve as the 7th full voting member of the ISGB, and shall be the only ISGB member with any decision-making authority over institute facilities and awards of grants made by the institute.*

(3) *Develop the budgets, financing plans, and cost control programs of the institute, as ratified by the ISGB.*

(4) *Lead discussions on the institute's annual and long-term strategy, as ratified by the ISGB.*

(5) *Supervise all annual reports and compliance with applicable public accountability requirements.*

(6) *Serve as a non-voting member of the Grants Committee and the Scientific Accountability Committee.*

(7) *Exercise veto power over any grants approved by both the Grants Committee and the Scientific Accountability Committee.*

(8) *Set and revise, as deemed necessary, the institute's processes, policies, and workflow, including the grant review process and intellectual property agreements policies, as ratified by the ISGB where applicable.*

(9) *Hire, direct, and manage the staff of the institute.*

(10) *Aim to recruit highly qualified scientific and medical talent to serve the institute on its committees, as ratified by the ISGB.*

(11) *Manage compliance with all rules and regulations of the institute, including the performance of any grant recipients.*

(12) *Manage and execute any intellectual property agreements and any other contracts pertaining to the institute or the research that it funds.*

(13) *Interact and communicate with government agencies, the California Legislature, the United States Congress, the California health care system, and the general public.*

(14) *Supervise the implementation of all ISGB decisions and oversee general matters related to the ISGB.*

(15) *Utilize any other powers or responsibilities delegated to the chief executive officer by the ISGB.*

(16) *The chief executive officer shall, at their sole discretion, hire a chief operating officer to assist and support the chief executive officer in the execution of their duties.*

152015. Grants Committee.

The institute shall have, and there is hereby established, a Grants Committee.

(a) Membership

(1) *The Grants Committee members shall be selected as follows:*

(A) *The chief executive officer shall select and nominate the candidates for membership in the Grants Committee.*

(B) *The members of the ISGB shall vote whether to ratify each candidate selected by the chief executive officer.*

(2) *The Grants Committee may have as many members as is deemed necessary by the chief executive officer and ISGB to respond to grant applications in a timely manner.*

(3) *The Grants Committee shall comprise a minimum of 3 members before grant award decisions can be made.*

(b) Qualifications

Notwithstanding any other qualifications established by the chief executive officer, all members of the Grants Committee shall satisfy at least one of the following qualifications:

(1) *Experience in an academic, non-profit, governmental, or industry position with demonstrated experience in a field that is relevant to any of the Key Funding Areas as provided in subdivisions (d) and (e) of Section 152030.*

(2) *Experience as a program manager, or equivalent, with demonstrated experience awarding grants in a field relevant to any of the Key Funding Areas as provided in subdivisions (d) and (e) of Section 152030.*

All Grants Committee members must adhere to the ethics and conflicts of interest standards as specified in Section 152035.

(c) Functions

(1) The Grants Committee shall construct a portfolio of grants to facilitate the institute's mission. This may include making some grants that are ambitious in scope, or of a transformational nature, as appropriate. Grants should be made with appropriate urgency and where needed breakthroughs are critical, the committee may invest in a diversity of approaches to the same problem when appropriate. Particular emphasis should be given to projects that accelerate the translation of research discoveries into practical applications.

(2) Together with the chief executive officer, the Grants Committee shall work to establish grant submission processes and grant appraisal criteria, which shall be subject to ratification by a vote of the ISGB, including:

(A) interim and final criteria, standards, and requirements for consideration in funding applications and for the awarding of research grants;

(B) recommendations regarding standards for the scientific and medical oversight of grants; and

(C) standards for the evaluation of grantees to ensure that they comply with all applicable requirements. Such standards shall mandate periodic reporting by grantees and shall authorize the Grants Committee to audit a grantee and forward any recommendations for further action to the chief executive officer, the Scientific Accountability Committee, and the ISGB.

(3) The committee may modify its recommendations regarding the criteria, standards, and requirements described in paragraphs (1) and (2) above, as needed.

(4) The committee shall review grant applications based on the criteria, requirements, and standards, and make rankings and determinations for the award of grants, subject to review by the Scientific Accountability Committee and final ratification by the chief executive officer.

(5) The committee may consult with external experts as necessary to improve processes and standards, and review awards.

(6) The committee shall conduct oversight, such as providing periodic progress reviews, of grantees to ensure compliance with the terms of the award and provide reports to the chief executive officer and ISGB together with any recommendations for subsequent action.

(7) The Committee shall conduct the grant evaluation process in compliance with all applicable safety, security, or ethics assessment procedures.

(d) Minimum Grant Application Review Process Standards

The institute shall establish a grant application review process that meets or exceeds the standards set forth below:

(1) The members of the Grants Committee shall review grant award applications for merit with a panel of at least 3 reviewers per application for grants under one million dollars (\$1,000,000) in total value, and a panel of at least 5 reviewers per application for grants over one million dollars (\$1,000,000) in total value.

(2) Any grant that is over one million dollars (\$1,000,000) in total value shall have first received the approval of at least 3 members of the Grants Committee prior to being awarded.

(3) An accelerated review process for any grant that is under two hundred fifty thousand dollars (\$250,000) in total value.

(4) The Grants Committee shall endeavor to complete the review process within 90 days of receipt of an application.

(5) Award recommendations shall be based upon a competitive evaluation which considers at least the following factors and criteria:

(A) A demonstrated record of achievement, in the area of research being funded, unless the research is determined by a majority of the Grants Committee to be a vital research opportunity.

(B) Importance of the problem to be addressed.

(C) A grant application that is clearly described, well-focused, and sufficiently comprehensive in its technical approach to achieve the stated objectives.

(D) Tasks to be carried out are well planned and expected outcomes are clearly described.

(E) Reasonable timelines for planned tasks.

(F) Ability of the applicant to execute the work.

(G) If applicable, whether the proposed grant would enable the technology under development to become economically viable.

(H) If applicable, the availability of matching funds from non-institute sources.

(I) In order to ensure that institute funding does not duplicate or supplant existing funding, a high priority shall be placed on applications that cannot, or are unlikely to, receive timely or sufficient funding from other sources, such as the National Institutes of Health and the Centers for Disease Control and Prevention.

(J) *Special consideration shall be given to grant applications that involve groups of applicants across disciplines joining together to apply for a grant with a large and ambitious scope, particularly in the Key Funding Areas of Economic Viability, Pilot Projects, and Demonstration Projects as described in subdivision (d) of Section 152030.*

(6) *The grant evaluation process shall contain:*

(A) *A minority report process whereby any dissenting opinion within the set of reviewers for a given grant is communicated to the chief executive officer and the Scientific Accountability Committee.*

(B) *An appeals process, whereby a grant applicant can request a reevaluation by the Grants Committee of their submission, should they disagree with the institute's decision not to award a grant to them. The process should include, at a minimum, the following aspects:*

(i) *The applicant should receive brief comments from reviewers of the Grants Committee (or, if applicable, from the Scientific Accountability Committee) indicating the reason(s) for rejection and any other relevant feedback.*

(ii) *The applicant may appeal the award rejection within 30 days of receiving the rejection.*

(iii) *Appeals may include consideration of material disputes of fact or material new information.*

152020. Scientific Accountability Committee.

The institute shall have, and there is hereby established, a Scientific Accountability Committee, which shall ensure compliance with best practices of protecting biosafety, biosecurity, and privacy interests.

(a) Membership

(1) *The Scientific Accountability Committee shall have a minimum of 3 members, appointed as follows:*

(A) *The chief executive officer shall select the candidates for membership in the Scientific Accountability Committee.*

(B) *The members of the ISGB shall vote whether to ratify each candidate selected by the chief executive officer.*

(2) *The Scientific Accountability Committee may have as many members as is deemed necessary by the chief executive officer and ISGB to respond to grant applications in a timely manner.*

(3) Members of the Scientific Accountability Committee may only be removed by a majority vote of the ISGB, upon recommendation of such removal from the chief executive officer.

(b) Qualifications

Notwithstanding any other qualifications established by the chief executive officer, Scientific Accountability Committee members shall meet at least one of the following qualifications:

(1) Demonstrated experience in the field of biosecurity or biological threat reduction research or policy.

(2) Demonstrated experience managing or implementing projects related to biosecurity or biological threat reduction, whether in academia, industry, government, or elsewhere.

(3) Demonstrated experience in the fields of data privacy, medical privacy, or genetic information privacy. Demonstrated record of defending the right to privacy against illegal surveillance preferred.

At least two members of the scientific accountability committee must meet criteria specified in paragraphs 1 or 2 of this subdivision, and at least one member of the scientific accountability committee must meet criterion in paragraph 3 of this subdivision.

(c) Functions

(1) The committee shall recommend procedures and standards for ensuring that institute funding is held to high standards of biosecurity, biosafety, and privacy. Any procedures and standards shall be subject to ratification by the ISGB. Such procedures and standards shall include, but not be limited to:

(A) A biosafety, biosecurity, and privacy risk assessment procedure for all grants approved by the Grants Committee, including screening for Areas of Concern.

(B) A requirement for all grant applicants to complete a risk/ benefit assessment for biosecurity, biosafety, and privacy risks as part of their grant application submission process.

(C) An enhanced risk/benefit assessment procedure for applications deemed to constitute Areas of Concern.

(D) The ability of Scientific Accountability Committee members, on the basis of these assessments and their own judgment, to prohibit the awarding of grants that are deemed an unacceptable biosafety, biosecurity, or privacy risk.

(E) Safety, security, and privacy standards to be abided by all successful grant applicants, including but not limited to those specified by the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern, or its successor policy.

(F) Regular review of funded projects deemed to constitute a potential biosafety, biosecurity, or privacy risk, including procedures for incorporating lessons learned into institute standards and procedures, and measures to rescind funding that is misused or later determined to present a serious biosafety, biosecurity, or privacy risk.

(G) Mitigation procedures to minimize the hazard of funded projects deemed to constitute a potential safety, security, or privacy risk.

(H) Regular review and update of committee procedures and standards, the institute's lists of Areas of Concern as provided in subdivision (e) of this section, and any related policies.

(2) Following establishment of procedures and standards of the committee, the Scientific Accountability Committee shall review grant award recommendations from the Grants Committee to enforce compliance, as described in subdivision (d) of this section. Grants should not be awarded until procedures and standards of the committee are established.

(d) Review Process

(1) Each grant award recommendation from the Grants Committee shall be reviewed by at least three members of the Scientific Accountability Committee, who shall assess its compliance with the institute's procedures and standards on safety, security, and privacy. Any individual reviewer on the Scientific Accountability Committee may veto any grant which in their determination violates these procedures and standards.

(2) Each grant award recommendation from the Grants Committee shall be reviewed by at least two experts in biosecurity and biosafety, possessing the qualifications described in paragraphs (1) and (2) of subdivision (b) of this section, and one expert in privacy, possessing the qualifications described in paragraph (3) of subdivision (b) of this section.

(3) Any grant award recommendation that any single Scientific Accountability Committee reviewer believes to constitute an Area of Potential Concern shall be subjected to an enhanced risk-benefit assessment, as detailed in subdivision (e) of this section.

(4) Any grant award determination that any single reviewer has determined to constitute an Area of Heightened Concern, or otherwise constitutes an unacceptable biosafety, biosecurity, or privacy risk, shall be vetoed by that reviewer, and shall not receive institute funding.

(e) Areas Subject to Additional Review

(1) Particular project areas, while potentially relevant to the Key Funding Areas of the institute, may pose a risk to the safety or security of the people of California. As such, they are designated "Areas of Concern," and shall be subject to additional scrutiny and restrictions during funding applications to the institute.

(2) As set forth in this subdivision, Areas of Concern shall be divided into two categories, "Areas of Potential Concern" and "Areas of Heightened Concern." Areas of Potential Concern

shall only be funded following a more extensive risk-benefit assessment, according to procedures and standards laid out by the Scientific Accountability Committee. Areas of Heightened Concern shall not receive institute funding under any circumstances.

(3) "Areas of Heightened Concern" means any project that aims, facilitates, or is deemed likely, to:

(A) Directly alter or enhance the transmissibility, virulence, stability, immune evasion, resistance to medical countermeasures, or tropism of any potential pandemic pathogen (hereinafter referred to as "PPP"), or otherwise alter its properties in a manner likely to make it less containable, less detectable, or more resistant to medical countermeasures (hereinafter referred to as "enhancement of PPPs");

(B) Generate or reconstitute an eradicated or extinct pathogen or other disease-causing agent, including but not limited to those listed in the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern.

(4) "Areas of Potential Concern" means any project that aims, facilitates, or is deemed likely, to:

(A) Accelerate the development of methods applicable to enhancement of PPPs;

(B) Increase or accelerate public dissemination of methods and information applicable to enhancement of PPPs;

(C) Increase the ability to predict the pathogenicity, or other dangerous properties, of a biological agent, including but not limited to its transmissibility, virulence, immune evasion, resistance to treatment, or tropism;

(D) Increase physical or informational access to PPPs;

(E) Otherwise constitute Dual Use Research of Concern, as defined by the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern, or any successor policy;

(F) Produce technology or methods that could be misused for mass surveillance, involuntary infringement of privacy, or other violations of rights and liberties.

(5) These restrictions shall apply irrespective of the aims or intentions of those proposing or carrying out the proposed projects, even if those intentions are directed towards preventing, or reducing the harm caused by, future outbreaks and pandemics.

(6) At the discretion of the ISGB, the ISGB may by majority vote elevate Areas of Potential Concern to be treated as Areas of Heightened Concern. Such Areas of Heightened Concern that were elevated by the ISGB may be demoted back to Areas of Potential Concern by a subsequent majority vote of the ISGB. Areas of Heightened Concern expressly set forth in paragraph 3 of this subdivision shall not be demoted to Areas of Potential Concern.

(7) *The ISGB, in consultation with the Scientific Accountability Committee, may by majority vote identify additional areas of research and development to be treated as Areas of Concern. Project areas to be treated as Areas of Concern which were added by vote of the ISGB may be removed by a subsequent majority vote of the same, but those Areas of Concern expressly included in this subdivision shall not be removed.*

(8) *A list of current Areas of Concern and program areas treated as Areas of Concern shall be made available to the public on the institute's website throughout the institute's operations.*

152025. Advisory Task Forces.

(a) Membership

The chief executive officer may appoint one or more advisory task forces to provide guidance to address specific areas under the institute's jurisdiction, including scientific, policy, ethical, financial, and technical matters.

(b) Functions

Any advisory task force may advise the ISGB and the chief executive officer, including but not limited to, scientific, policy, financial, ethical, and technical matters under the institute's jurisdiction. Members of the advisory task force shall not have voting rights on the ISGB, Grants Committee, or Scientific Accountability Committee of the institute.

(c) Operations

(1) *Any advisory task forces shall be advisory only, shall have no decision-making authority on institute matters, and shall meet in public when they vote to make any recommendations.*

(2) *Members of the advisory task forces shall not review, comment upon, or have jurisdiction over, any individual grant approval.*

152030. Operations.

(a) Legal Actions and Liability

(1) *Based upon ISGB standards, institute grantees shall be required to indemnify, insure, and hold the institute harmless against any and all losses, claims, damages, expenses, or liabilities, including attorneys' fees, arising from research conducted by the grantee pursuant to the grant, and grantees shall name the institute as an additional insured and submit proof of such insurance.*

(2) *Given the scientific, medical, and technical nature of the issues facing the ISGB, and notwithstanding Section 11042 of the Government Code, the institute is authorized to retain outside counsel when the ISGB determines that the institute requires specialized services.*

(3) *The institute may enter into any contracts or obligations which are authorized or permitted by law.*

(4) *The institute may sue and be sued.*

(b) Personnel and Compensation

(1) *The ISGB shall, from time to time, determine the total number of authorized employees for the institute, up to a maximum of 70 full-time, paid employees.*

(2) *Each member of the ISGB, except the chief executive officer, shall receive a per diem of two hundred dollars (\$200) per day (adjusted annually for cost of living) for each day actually spent in the discharge of the member's duties, plus reasonable and necessary travel and other expenses incurred in the performance of the member's duties.*

(3) *The ISGB shall establish daily consulting rates and expense reimbursement standards for the non-employee members of all of its committees.*

(4) *Notwithstanding Section 19825 of the Government Code, the ISGB shall set compensation for the chief executive officer and other officers, and for the scientific, medical, technical, and administrative staff of the institute within the range of compensation levels for executive officers and scientific, medical, technical, and administrative staff of medical schools within the University of California system and comparable nonprofit academic and research institutions.*

(c) Committees and Meetings

(1) Committee Members

(A) *Within 90 days of the chief executive officer's hiring, the institute shall endeavor to recruit and retain sufficient Grants Committee and Scientific Accountability Committee members such that the committees may begin to operate.*

(2) Meetings

(A) *The ISGB shall hold at least two public meetings per year, one of which will be designated as the institute's annual meeting. The ISGB may hold additional meetings as it determines are necessary or appropriate.*

(B) *The Grants Committee and Scientific Accountability Committee shall each hold at least four meetings per year, one of which shall be designated as its annual meeting, except as otherwise determined by the institute.*

(d) Key Funding Areas

(1) *The institute is authorized to make grants in the following critical areas of research, referred to collectively as "Key Funding Areas." Investments shall be made across technology readiness levels, including, but not limited to, concept generation, feasibility studies, research*

and development, advanced technology development, product development, system integration, and regulatory approval. Key Funding Areas include:

(A) Public Health Integration: Because decision makers in public health response and policy need access to the best data on pathogens and outbreaks in order to take timely action, while at the same time safeguarding privacy, the institute may award grants concerning:

(i) Clinical metagenomics data: Modernized tools and processes for linking clinical samples and pathogen metagenomic data with de-identified metadata, while safeguarding privacy, for the purpose of contact tracing and outbreak containment.

(ii) Data integration: Systems that integrate pathogen metagenomic data from diverse sources (including clinical, sentinel, environmental, and agricultural) to improve detection and characterization of pathogens. Modernized tools for automatic reporting of metagenomic sequences to relevant surveillance systems and databases.

(iii) Genomic epidemiology: Integrating epidemiologic and metagenomic data to detect and characterize pathogens and outbreaks, describe transmission dynamics, and conduct contact tracing.

(B) Security and Privacy: Because the data and systems involved in pathogen metagenomics and pandemic prevention are sensitive, the institute may award grants concerning:

(i) Privacy preserving technology: Software, hardware, or other solutions that protect personal information associated with pathogen metagenomic data.

(ii) Encryption: Methods and implementations of encryption for all data and systems involved in metagenomics.

(iii) Cybersecurity: Funding to address the potential for or actual malicious destruction, misuse, or exploitation of valuable information, processes, and material related to pathogen metagenomics.

(C) Standardization: Because interoperability between components and systems involved in pathogen detection and pandemic prevention is important for operational viability, the institute may award grants concerning:

(i) Hardware: Systems or designs that modularize sample acquisition, sample preparation, sequencing, and analysis devices such that they can be integrated into a single, reconfigurable, automated device for pathogen metagenomics.

(ii) Software: Standardized software protocols, designs, or systems that can serve as an interface to many different hardware systems involved in pathogen metagenomics.

(iii) *Data: Development of standards for pathogen metagenomic data quality and interoperability, including sequence quality.*

(iv) *Quality: Standards, references, methods, tools, protocols, and technology to advance the reliability, consistency, and universality of genomic sequencing for pathogen detection.*

(v) *Reporting: Development of standards for reporting, especially for the purpose of reporting metagenomic pathogen detection results to relevant public health authorities.*

(D) *Automation: Because the processes involved in sequencing a sample are complex and require hours of skilled lab technician labor, the institute may award grants concerning:*

(i) *Sample acquisition: Automated devices to collect and store samples with minimal or no technician involvement.*

(ii) *Sample preparation: Automated devices that run high-throughput pathogen-agnostic metagenomic sample preparation reliably with minimal or no technician involvement.*

(iii) *Sample use minimization: reducing the number of, or miniaturizing, reactions to minimize reagent use and sample use in pathogen-agnostic metagenomic sample preparation*

(iv) *Development of non-proprietary components and consumables: Devices capable of using generic or interchangeable components and consumables.*

(E) *Sequencers: Because sequencing instruments must become smaller, faster, and more robust, the institute may award grants concerning:*

(i) *Throughput: Sequencers that can process more samples in parallel and process samples more quickly.*

(ii) *Accuracy: Improved sequencing read accuracy and length.*

(iii) *Size and weight: Miniaturized sequencers and components.*

(iv) *Power: Lower power requirements to run sequencers.*

(v) *Robustness: Ruggedized, reliable, temperature-tolerant, and fault-tolerant sequencers, such as sequencers able to operate in resource-constrained environments.*

(vi) *Novel sequencing methods: Including, but not limited to solid state sequencers and direct sequencing, such as direct RNA sequencing.*

(F) Sample Preparation: Because the reagents, flow cells, and other consumables involved in sample preparation for metagenomic sequencing add to sequencing's complexity and impact data quality, the institute may award grants concerning:

(i) Reduced reagent requirements: The development of sample preparation processes that reduce the cost, complexity, and temperature requirements of reagents.

(ii) In situ reagent production: Methods to inexpensively produce reagents at the point of sequencing.

(iii) Reagent-free sequencing: Methods and devices that allow for sequencing entirely without the use of reagents.

(G) Analysis: Because pathogen metagenomics can be computationally intensive and can require skilled bioinformatician labor, the institute may award grants concerning:

(i) Bioinformatic algorithms and tools: Scalable metagenomic bioinformatics algorithms, machine learning models, pipelines, and systems capable of efficiently handling large volumes of data.

(ii) Data security: Securely screen sequences without disclosing information about hazardous agents.

(iii) Data storage and distributed systems: Efficient pathogen metagenomic data storage, access, integration, and interpretation across multiple sequencing sites.

(iv) Hardware: Specialized hardware for base calling, alignment, and metagenomic assembly.

(H) Clinical Applications: Because it can be effective for early pathogen detection to collect samples and sequence pathogens when people are already seeking a diagnosis and medical care, the institute may award grants concerning:

(i) Point-of-care: Metagenomic sequencing available at hospitals and care providers' offices for screening and infectious disease diagnosis.

(ii) Personal diagnostics: At-home/point-of-person infectious disease diagnostics using metagenomic sequencing.

(I) Sentinel Testing: Because human populations at a higher risk of contracting and spreading a pathogen could be screened regularly for infection with metagenomic sequencing, the institute may award grants concerning the regular screening for infection in, but not limited to, the following groups:

(i) *Biomedical researchers and technicians: Those who handle infectious biological agents, particularly in high-biosafety-level (or equivalent) labs.*

(ii) *Field epidemiologists: Those closely involved in the investigation of new outbreaks.*

(iii) *Care providers: Medical professionals who come into close contact with patients, including at skilled nursing facilities.*

(iv) *Blood donors: Additional screening for known and novel pathogens in blood given by volunteer donors.*

(v) *Ports of entry workers: Those who work at airports, seaports, and land crossings.*

(vi) *Agricultural workers: Those who work in close contact with livestock, including those at high density livestock production facilities.*

(J) *Environmental Monitoring: Because locations where pathogens are concentrated or easily transmitted can be good candidates for pathogen metagenomic sequencing, the institute may award grants concerning:*

(i) *Wastewater: Sampling of municipal wastewater and building wastewater systems.*

(ii) *Waterways: Sampling from natural bodies of water, municipal water supply lines, etc.*

(iii) *Vectors: Automated sampling of arthropod vectors (mosquitos, fleas, ticks, sand flies, etc.), including partnerships with mosquito abatement and vector control districts in California.*

(K) *Agricultural Monitoring: Because agricultural pathogens and invasive species pose a large threat to California's well-being and economy, the institute may award grants concerning:*

(i) *Plants: Sampling from plants to detect and contain agricultural pathogens and invasive species and prevent loss of crops and protect native species.*

(ii) *Livestock: Sampling from animals at high density livestock production facilities, including chicken, turkey, cattle, pigs, and fish.*

(iii) *Food Safety: Sampling across the food production supply chain ("farm to table") to detect the source of a food-borne pathogen.*

(L) *Antimicrobial Resistance: Because certain pathogens are growing increasingly resistant to antimicrobials and these antimicrobial resistant pathogens may be detected using metagenomic sequencing, the institute may award grants concerning:*

(i) *Rapid detection: Broad and rapid detection of antibacterial and antifungal resistance and source tracking using metagenomic sequencing.*

(ii) *Monitoring: Strategic monitoring of antimicrobial genes using metagenomic sequencing across different contexts. These contexts may include, but are not limited to, hospital-acquired infections, skilled nursing facilities, and environmental sources.*

(M) *End-to-end testing: Funding for the integration and testing of the various components of pathogen metagenomic sequencing, from sample acquisition to public health integration and end user reporting.*

(N) *Clinical Studies: Funding for clinical research, clinical trials, and clinical utility studies to evaluate, facilitate regulatory approval of, and support adoption of pathogen metagenomic sequencing applications, such as diagnostics, related to biological threat risk reduction as indicated from subparagraphs (C) to (N).*

(O) *Demonstration and Pilot Projects: Funding for pathogen metagenomic sequencing demonstration and pilot projects and operational trials to test, evaluate, and refine understanding of implementational barriers and end user needs for applications related to biological threat risk reduction as indicated from subparagraphs (A) to (M).*

(P) *Regulatory Approval and Clearance: Funding for the activities required to accelerate regulatory clearance or approval of systems or methods related to metagenomic sequencing, such as Food and Drug Administration clearance or approval, Clinical Laboratory Improvement Amendments certification, or similar.*

(Q) *Economic Viability: Seed funding for economic analysis and promising technologies to be deployed in an economically sustainable manner, following a Small Business Innovation Research ("SBIR") model, Small Business Technology Transfer ("STTR") model, or similar.*

(R) *Talent Development: Investments in the next generation of metagenomic sequencing professionals. These investments may include, but are not limited to, fellowships, internships, training programs, and visiting scholar programs.*

(S) *Facilities: Pathogen-agnostic metagenomic sequencing centers of excellence at nonprofit or government entities, to ensure necessary research facilities to pursue the institute's Key Funding Areas.*

(e) *The ISGB may, by a majority vote, identify other areas of research to be treated as Key Funding Areas, provided that such areas further the purposes of the institute as set forth in Article XXXVI of the California Constitution. A list of Key Funding Areas, together with any areas of research added by the ISGB, shall be made available to the public on the institute's website, throughout the institute's operations.*

(f) *The chief executive officer and Grants Committee shall have the authority to prioritize amongst the list of Key Funding Areas set forth in this section or as adopted by the ISGB based*

on a number of factors, including but not limited to, importance, the availability of other funding mechanisms, and academic and scientific merit of grant applications.

(g) The chief executive officer shall have the authority to hire either full-time employees of the institute or contract with individuals or organizations to provide consulting services to grants recipients in Key Funding Areas, including but not limited to, Regulatory Approval and Clearance, and Economic Viability, as set forth in this section.

152035. Ethics, Conflict of Interest, Safety, and Accountability.

The following set of standards shall apply to all institute operations to ensure the transparent, equitable, safe, and effective deployment of public funds.

(a) Conflicts of Interest

(1) Unless otherwise provided in this division, no member of the ISGB, the Scientific Accountability Committee or any Advisory Task Force shall make, participate in making, or in any way attempt to use their official position to influence a decision to approve or award a grant. The veto power of the Scientific Accountability Committee shall not constitute making, participating in making or attempting to use their official position to influence a decision to approve or award a grant.

(2) No employee of the institute or member of the Grants Committee shall make, participate in making, or in any way attempt to use their official position to influence a decision to approve or award a grant to any entity which the member or employee is affiliated or employed, or has received any payment or other compensation from in the last 12 months, or has any financial interest. However, an employee or member of the Grants Committee may participate in a decision to approve or award a grant to a nonprofit entity in the same field as their past employer, or in the same field as an entity in which they have a financial interest.

(3) The Political Reform Act, Title 9 (commencing with Section 81000) of the Government Code, shall apply to the institute and to the ISGB, except as provided in this section.

(4) All employees and members of the Grants Committee of the institute who have a financial interest in decisions to approve or award a grant, shall disclose their potential conflicts of interest to the ethics officer, and recuse themselves from participation if necessary.

(5) The ISGB shall develop and adopt financial conflict of interest and gift disclosure requirements for ISGB, the Scientific Accountability Committee, and any Advisory Task Force members.

(6) The ISGB may adopt further conflict of interest rules to govern the institute and its employees, based on standards applicable to members of scientific review committees of the National Institutes of Health.

(7) The term "financial interest" means a financial interest as defined in the Political Reform Act (Title 9 (commencing with Section 81000) of the Government Code).

(8) The adoption of standards is not a decision subject to this section.

(9) Section 1090 of the Government Code shall not apply to any grant or contract made by the institute except where both of the following conditions are met:

(A) The grant or contract directly relates to services to be provided by any member of the Grants Committee or the entity the member represents or financially benefits the member or the entity they represent.

(B) The Grants Committee member fails to recuse himself or herself from making, participating in making, or in any way attempting to use their official position to influence a decision on the grant loan or contract.

(10) Members of the ISGB, the Scientific Accountability Committee and any Advisory Task Force shall not be considered public officials, employees, or consultants for purposes of the Political Reform Act (Title 9 (commencing with Section 81000) of the Government Code), Section 1090 and 19990 of the Government Code, and Sections 10516 and 10517 of the Public Contract Code.

(b) Incompatible Service

(1) Because the ISGB and any Advisory Task Force are purely oversight organizations and have no final grantmaking authority, and are not involved in making grants, service as a member of the ISGB or any Advisory Task Force by a representative or employee of a nonprofit academic institution or university, a research institution, nonprofit entity, or a commercial entity, shall not be deemed to be inconsistent, incompatible, in conflict with, or inimical to the duties of the member as a representative or employee of that organization, institution, or entity, and shall not result in the automatic vacation of either such office, nor will it preclude such nonprofit academic institution or university, research institution, nonprofit entity, or commercial entity from receiving grants, loans, or contracts from the institute.

(2) The ISGB shall develop and adopt incompatible service policies for Scientific Accountability Committee members.

(c) Post-institute Service Prohibition

(1) For a period of 12 months after leaving the institute, no Grants Committee member or employee of the institute who is required to file a Statement of Economic Interests under the Political Reform Act shall be allowed to receive or be promised compensation from, nor be employed by, any entity which received a grant from the institute during the member or employee's period of service with the institute where the Grants Committee member or employee was directly involved in the award of the grant.

(2) For a period of 12 months after leaving the institute, no Grants Committee member or employee of the institute who is required to file a Statement of Economic Interests under the Political Reform Act shall be allowed to communicate, for compensation, with the institute for the purpose of influencing any grant.

(3) *No Grants Committee member or employee of the institute shall be allowed to receive compensation from any grant issued or entered into by the institute during the member or employee's period of service with the institute.*

(4) *With the exception of the chief executive officer, the post-institute service prohibitions shall not apply to members of the ISGB, the Scientific Accountability Committee or any Advisory Task Force.*

(d) Ethics Officer

(1) *The ISGB shall hire an ethics officer or appoint one from among the staff of the institute. The ethics officer shall be responsible for educating and training members and employees on applicable ethics rules and procedures, such as, educating institute members on the risks posed by the Areas of Concern, developing and proposing updated ethics rules and standards to the ISGB, and assisting in the identification and prevention of conflicts of interest and other ethics rules.*

(2) *The Ethics Officer shall report directly to the ISGB.*

(3) *The ISGB and Ethics Officer shall establish an institute whistleblower protection and complaint process based upon the California Whistleblower Protection Act (Article 3 (commencing with Section 8547) of Chapter 6.5 of Division 1 of Title 2 of the Government Code).*

(e) Annual Public Report

The institute shall issue an annual report to the public which sets forth the institute's activities, grants awarded, grants in progress, research accomplishments, and future program directions. Each annual report shall include, but not be limited to, the following: the number and dollar amounts of research and facilities grants; the grantees for the prior year; the institute's administrative expenses; an assessment of the availability of funding for research from sources other than the institute; a summary of research findings, including promising new research areas; an assessment of the relationship between the institute's grants and the overall strategy of its research program; and a report of the institute's strategic research and financial plans.

(f) Annual Independent Financial Audit by State Controller and Annual Meeting

The institute shall annually commission an independent financial audit of its activities from a certified public accounting firm, which shall be provided to the State Controller, who shall review the audit and annually issue a public report of that review. The State Controller shall hold a public meeting, with appropriate notice, and with a formal public comment period. The State Controller shall evaluate public comments and include appropriate summaries in the annual report.

(g) Open Meetings

(1) The Bagley-Keene Open Meeting Act, Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code, shall apply to all meetings of the institute, including the ISGB, the Scientific Accountability Committee, the Grants Committee, and any Advisory Task Force, except as otherwise provided in this section. The institute shall disclose all awarded grants in public meetings, award all grants, loans, and contracts in public meetings, and adopt all governance, scientific, medical, and regulatory standards in public meetings.

(2) The institute may conduct closed sessions as permitted by the Bagley-Keene Open Meeting Act, under Section 11126 of the Government Code. In addition, the institute may conduct closed sessions when it meets to consider or discuss:

(A) Matters involving information relating to patients or medical or scientific research subjects, the disclosure of which would constitute an unwarranted invasion of personal privacy.

(B) Matters involving confidential intellectual property or work product, whether patentable or not, including, but not limited to, any formula, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information, which is not patented, which is known only to certain individuals who are using it to fabricate, produce, or compound an article of trade or a service having commercial value and which gives its user an opportunity to obtain a business advantage over competitors who do not know it or use it.

(C) Matters involving scientific data, analyses, or other research products not yet formally published in the academic literature.

(D) Matters concerning the appointment, employment, performance, compensation, or dismissal of institute officers and employees. Action on compensation of the institute's officers and employees shall only be taken in open session.

(E) Matters believed to pose a biosecurity risk to the people of California.

(h) Open Records

(1) The California Public Records Act, Article 1 (commencing with Section 6250) of Chapter 3.5 of Division 7 of Title 1 of the Government Code, shall apply to all records of the institute, except as otherwise provided in this section.

(2) Nothing in this section shall be construed to require disclosure of any records that are any of the following:

(A) Personnel, medical, or similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy.

(B) Records containing or reflecting confidential intellectual property or work product, whether patentable or not, including, but not limited to, any formula, plan, pattern,

process, tool, mechanism, compound, procedure, production data, or compilation of information, which is not patented, which is known only to certain individuals who are using it to fabricate, produce, or compound an article of trade or a service having commercial value and which gives its user an opportunity to obtain a business advantage over competitors who do not know it or use it.

(C) Scientific working papers or research data that have not been published in a scientific peer-reviewed publication.

(D) Matters believed to pose a biosecurity risk to the people of California.

(i) Competitive Bidding

(1) The institute shall, except as otherwise provided in this section, be governed by the competitive bidding requirements applicable to the University of California, as set forth in Article 1 through 5 (commencing with Section 10500) of Chapter 2.1 of Part 2 of Division 2 of the Public Contract Code.

(2) For all institute contracts, the institute shall follow the procedures required of the Regents by Article 1 through 5 (commencing with Section 10500) of Chapter 2.1 of Part 2 of Division 2 of the Public Contract Code with respect to contracts let by the University of California.

(3) The requirements of this section shall not be applicable to grants made by the institute.

(4) Except as provided in this section, the Public Contract Code shall not apply to contracts let by the institute.

(j) Preference for California Suppliers

The ISGB shall establish standards to ensure that grantees purchase goods and services from California suppliers to the extent reasonably possible.

(k) Funding of California Entities

Grant applications may be accepted from public and private universities in California; cities, counties, and special districts of the state; and non-profit organizations and private industry applicants with a physical presence in California.

(l) General Ethics Standards

(1) The ISGB shall ensure the institute operations are governed by ethical standards in all areas of its operations, and in addition to other standards in this act, shall establish standards as follows:

(A) *Standards for grant ethics reviews, such as obtaining the informed consent of research participants, which shall be based on the standards in place on January 1, 2021, for all research funded by the National Institutes of Health.*

(B) *Standards to assure compliance with state and federal privacy laws.*

(C) *Standards permitting reimbursement for necessary expenses.*

152040. Appropriation and Allocation of Funding.

Moneys in the California Pandemic Early Detection and Prevention Fund created pursuant to Section 19602.7 of the Revenue and Taxation Code shall be allocated as follows:

(a) *For the ten year period following the enactment of this Act, hereafter referred to as the "revenue generating period", no more than 5 percent of the institute's annual revenues shall be used for institute administrative purposes and facilities, and no more than 3 additional percent of the institute's annual revenues shall be used for grant implementation costs, including the development, administration, and oversight of the grant making process and the operations of the committees of the institute.*

(b) *After the cessation of the revenue generating period specified in subdivision (a), the institute shall use no more than 6 percent of the institute's average annual revenues over the aforementioned revenue generating period for institute administrative purposes, and no more than 4 additional percent of the institute's average annual revenues over the revenue generating period shall be used for grant implementation costs, including the development, administration, and oversight of the grant making process and the operations of the committees of the institute.*

(c) *In any single year, any new research funding to any single grantee is limited to no more than 5 percent of the institute's annual funds. This limitation shall be considered separately for each new proposal and each calendar year of the grant. This requirement shall apply unless the chief executive officer approves, and the ISGB ratifies, a higher limit for that grantee.*

(d) *The institute shall limit grantees' indirect costs to 25 percent of a research award, excluding amounts included in a facilities award, except that the indirect cost limitation may be increased by the amount by which the grantee provides matching funds in excess of 20 percent of the grant amount.*

(e) *Recognizing the priority of building research facilities that enable the pursuit of projects in the institute's Key Funding Areas, up to 10 percent of the institute's annual funds may be awarded for building scientific and medical research facilities of nonprofit entities.*

(f) *Recognizing the priority of translating scientific advances into large-scale, "real-world," systems that can detect novel pathogens and prevent pandemics, the institute shall endeavor to allocate at least 50 percent of the total value of grants awarded each year to projects in the Key Funding Areas of Clinical Studies, Pilot Projects, Demonstration Projects, Regulatory Approval and Clearance, and Economic Viability. If the institute is unable to meet this goal in a given year, the chief executive officer and the ISGB shall issue a report outlining the reasons the*

institute was unable to meet the goal and outline a set of corrective actions to ensure that the institute is able to meet the goal in future years. This document will be included in that year's institute annual report.

(g) Notwithstanding any other provisions in this act, the institute shall not be required to award all of its available funds in any given year. Any excess funds at the end of the institute's fiscal year shall be added to the funds available for the subsequent year, and so forth until the funds are exhausted. The institute shall continue to operate until all its funds are exhausted.

(h) To enable the institute to commence operating during the first six months following the adoption of the measure adding this chapter, there is hereby appropriated from the General Fund a start-up loan to the institute of ten million dollars (\$10,000,000) for initial administrative and implementation costs. This loan to the institute pursuant to this appropriation shall be repaid to the General Fund within 24 months from the institute's funds.

CHAPTER 2

Definitions

152050. As used in this division and in Article XXXVI of the California Constitution, the following terms have the following meanings:

(a) "Advanced market commitment" means a binding contract, typically offered by a government or other financial entity, used to guarantee a viable market for a product once it is successfully developed.

(b) "Demonstration project" means a project deployed for real-world, operational use, for purposes including demonstrating the project's utility, including clinical utility, and studying its performance under operational conditions.

(c) "Dual-use research of concern" means life sciences research that can be reasonably anticipated to provide knowledge, information, products, or technologies that could be misapplied to pose a significant threat with broad potential consequences to public health.

(d) "Economic Viability" means translation of emerging technologies into economically viable products and making them available on the market.

(e) "Facilities" means buildings, building leases, or capital equipment.

(f) "Flow cell" means the core reaction chamber in which the biochemical processes occur for nucleic acid sequencing.

(g) "Grant" means any funding mechanism used by the institute, including, but not limited to, a grant, loan, guarantee, discount for consulting services, advanced market commitment, or inducement prize.

(h) "Grantee" means a recipient of a grant from the institute. All University of California grantee institutions shall be considered as separate and individual grantee institutions.

- (i) *“Immune evasion” means a pathogen’s capacity to evade a human immune response.*
- (j) *“Indirect costs” means the recipient’s costs in the administration, accounting, general overhead, and general support costs for implementing a grant of the institute.*
- (k) *“Inducement prize” means a competition that awards a prize for the accomplishment of a feat, usually of science or engineering.*
- (l) *“Institute” means the California Pandemic Early Detection and Prevention Institute.*
- (m) *“Metagenomic sequencing” or “metagenomics” means a pathogen-agnostic method used to sequence, align, classify, and assemble nucleic acids from multiple organisms and cell types in a biological sample for the detection of pathogens.*
- (n) *“Microfluidics” means the physics, manipulation, and study of minute amounts of fluids.*
- (o) *“Pathogen-agnostic” means an approach that does not assume any particular known pathogen and can apply to both known and unknown pathogens.*
- (p) *“Pathogenicity” is the capacity of a pathogen to cause disease.*
- (q) *“Pilot project” means a small-scale preliminary study conducted to evaluate feasibility, duration, cost, or adverse events, and improve upon the study design prior to performance of a larger scale project.*
- (r) *“Potential pandemic pathogens” means viruses, viral families, bacteria, and other microorganisms that are likely highly transmissible and capable of wide, uncontrollable spread in human populations and likely highly virulent, making them likely to cause significant morbidity or mortality in humans.*
- (s) *“Sample preparation” means the way a sample is modified prior to sequencing and analysis.*
- (t) *“Small Business Innovation Research” means a United States Government program, coordinated by the Small Business Administration, intended to help certain small businesses conduct research and development.*
- (u) *“Small Business Technology Transfer” means a United States Government program, coordinated by the Small Business Administration, intended to expand public/private sector partnerships between small businesses and non-profit U.S. research institutions.*
- (v) *“Technology Readiness Level” means a method for estimating the maturity of technologies that helps determine the type of investments and initiatives required to advance their development. The concept was originally formulated at NASA and is currently used by multiple funding entities and industries.*
- (w) *“Transmissibility” means a pathogen’s capacity to pass from one organism to another.*
- (x) *“Tropism” means the capability of a virus to infect a particular cell type, tissue, or host.*

(y) “Virulence” means the severity of disease a pathogen inflicts when it infects a human host.

SECTION 6. Section 17043.5 is added to the Revenue and Taxation Code, to read:

17043.5.

(a) *For each taxable year beginning on or after January 1, 2023, in addition to any other taxes imposed by this part, an additional tax shall be imposed at the rate of 0.75 percent on that portion of a taxpayer’s taxable income in excess of five million dollars (\$5,000,000).*

(b) *For purposes of applying Part 10.2 (commencing with Section 18401) of Division 2, the tax imposed under this section shall be treated as if imposed under Section 17041.*

(c) *The following shall not apply to the tax imposed by this section:*

(1) *The provisions of Section 17041, relating to filing status and recomputation of the income tax brackets.*

(2) *The provisions of Section 17045, relating to joint returns.*

(d) *No credits otherwise allowable under any provision of Part 10 shall be allowed against the tax imposed by this section.*

(e) *This section shall become inoperative 10 years after the effective date of the act adding this section and shall be repealed 11 years after the effective date of the act adding this section.*

SECTION 7. Section 19602 of the Revenue and Taxation Code is amended to read:

Except for amounts collected or accrued under Sections 17935, 17941, 17948, 19532, and 19561, and revenues deposited pursuant to Section 19602.5, *and revenues deposited pursuant to Section 19602.7*, all moneys and remittances received by the Franchise Tax Board as amounts imposed under Part 10 (commencing with Section 17001), and related penalties, additions to tax, and interest imposed under this part, shall be deposited, after clearance of remittances, in the State Treasury and credited to the Personal Income Tax Fund.

SECTION 8. Section 19602.7 is added to the Revenue and Taxation Code, to read:

19602.7.

(a) *There is hereby created in the State Treasury the California Pandemic Early Detection and Prevention Fund (“CPDI Fund”). The estimated revenue from the additional tax imposed under Section 17043.5 for the applicable fiscal year, as determined under subparagraph (B) of paragraph (3) of subdivision (c), shall be deposited to the CPDI Fund on a monthly basis, subject to an annual adjustment as described in this section.*

(b) (1) *Beginning with fiscal year 2022–2023 and for each fiscal year thereafter, the Controller shall deposit on a monthly basis in the CPDI Fund an amount equal to the applicable percentage of net personal income tax receipts as defined in paragraph (4).*

(2) (A) *Except as provided in subparagraph (B), the applicable percentage referred to in paragraph (1) shall be 0.80 percent.*

(B) *For fiscal year 2022–2023, the applicable percentage shall be 0.44 percent.*

(3) *Beginning with fiscal year 2024–2025, monthly deposits to the CPDI Fund pursuant to this subdivision are subject to suspension pursuant to subdivision (f).*

(4) *For purposes of this subdivision, “net personal income tax receipts” refers to amounts received by the Franchise Tax Board and the Employment Development Department under the Personal Income Tax Law, as reported by the Franchise Tax Board to the Department of Finance pursuant to law, regulation, procedure, and practice (commonly referred to as the “102 Report”) in effect on the effective date of the act establishing this section.*

(c) *No later than March 1, 2024, and each March 1 thereafter, the Department of Finance, in consultation with the Franchise Tax Board, shall determine the annual adjustment amount for the following fiscal year.*

(1) *The “annual adjustment amount” for any fiscal year shall be an amount equal to the amount determined by subtracting the “revenue adjustment amount” for the applicable revenue adjustment fiscal year, as determined by the Franchise Tax Board under paragraph (3), from the “tax liability adjustment amount” for applicable tax liability adjustment tax year, as determined by the Franchise Tax Board under paragraph (2).*

(2) (A) (i) *The “tax liability adjustment amount” for a tax year is equal to the amount determined by subtracting the estimated tax liability increase from the additional tax imposed under Section 17043.5 for the applicable year under subparagraph (B) from the amount of the actual tax liability increase from the additional tax imposed under Section 17043.5 for the applicable tax year, based on the returns filed for that tax year.*

(ii) *For purposes of the determinations required under this paragraph, actual tax liability increase from the additional tax means the increase in tax liability resulting from the tax of 0.75 percent imposed under Section 17043.5, as reflected on the original returns filed by October 15 of the year after the close of the applicable tax year.*

(iii) *The applicable tax year referred to in this paragraph means the 12-calendar month taxable year beginning on January 1 of the year that is two years before the beginning of the fiscal year for which an annual adjustment amount is calculated.*

(B) (i) *The estimated tax liability increase from the additional tax for the following tax years is:*

<i>Tax Year</i>	<i>Estimated Tax Liability Increase from the Additional Tax</i>
2023	\$1,000 million
2024	\$1,050 million
2025	\$1,103 million
2026	\$1,158 million

(ii) The “estimated tax liability increase from the additional tax” for the tax year beginning in 2027 and each tax year thereafter shall be determined by applying an annual growth rate of 5 percent to the “estimated tax liability increase from additional tax” of the immediately preceding tax year.

(3) (A) The “revenue adjustment amount” is equal to the amount determined by subtracting the “estimated revenue from the additional tax” for the applicable fiscal year, as determined under subparagraph (B), from the actual amount transferred for the applicable fiscal year.

(B) (i) The “estimated revenue from the additional tax” for the following applicable fiscal years is:

<i>Applicable Fiscal Year</i>	<i>Estimated Revenue from Additional Tax</i>
2022–23	\$560 million
2023–24	\$1,028 million
2024–25	\$1,080 million
2025–26	\$1,134 million

(ii) The “estimated revenue from the additional tax” for applicable fiscal year 2025–26 and each applicable fiscal year thereafter shall be determined by applying an annual growth rate of 5 percent to the “estimated revenue from the additional tax” of the immediately preceding applicable fiscal year.

(iii) The applicable fiscal year referred to in this paragraph means the fiscal year that is two years before the fiscal year for which an annual adjustment amount is calculated.

(d) The Department of Finance shall notify the Legislature and the Controller of the results of the determinations required under subdivision (c) no later than 10 business days after the determinations are final.

(e) If the annual adjustment amount for a fiscal year is a positive number, the Controller shall transfer that amount from the General Fund to the CPDI Fund on July 1 of that fiscal year.

(f) If the annual adjustment amount for a fiscal year is a negative number, the Controller shall suspend monthly transfers to the CPDI Fund for that fiscal year, as otherwise required by

paragraph (1) of subdivision (b), until the total amount of suspended deposits for that fiscal year equals the amount of the negative annual adjustment amount for that fiscal year.

SECTION 9. Section 19602.8 is added to Revenue and Taxation Code, to read:

19602.8.

(a) For the 2022-23 fiscal year, 20 percent of the monthly deposits made pursuant to paragraph (1) of subdivision (b) of Section 19602.7 shall be transferred into the Revenue Stabilization Account, which is hereby created within the California Pandemic Early Detection and Prevention Fund ("CPDI Fund") created by Section 19602.7 of this code.

(b) Beginning with the 2023-24 fiscal year and for each fiscal year thereafter until 10 years after the effective date of the act adding this section, except as provided in subdivisions (c) and (d), 10 percent of the monthly deposits made pursuant to paragraph (1) of the subdivision (b) of Section 19602.7, or an amount in addition to 10 percent as determined by the chief executive officer of the Independent Scientific Governing Board established by Division 121 (commencing with Section 152000) of the Health and Safety Code, shall be transferred into the Revenue Stabilization Account.

(c) The transfers made pursuant to subdivision (b) shall be suspended for any month during a fiscal year when the balance of the Revenue Stabilization Account exceeds \$500 million dollars.

(d) The transfers made pursuant to subdivision (b) shall be suspended during a fiscal year for which the Director of Finance estimates at the May Revision of the state budget for that fiscal year that monthly deposits made pursuant to paragraph (1) of the subdivision (b) of Section 19602.7 will be more than 5 percent below the total of deposits for the prior fiscal year. Such suspension shall remain in effect for the subsequent fiscal year unless the Director of Finance estimates at the May Revision of the state budget for that subsequent fiscal year that monthly deposits made pursuant to paragraph (1) of the subdivision (b) of Section 19602.7 shall be at least 100 percent of the total of deposits for the fiscal year prior to the fiscal year for which the suspension of transfers was initially imposed.

(e) For any fiscal year for which transfers are suspended pursuant to subdivision (d), up to one-half of the balance of the Revenue Stabilization Account may be transferred during that fiscal year to the CPDI Fund for use for the purposes of the California Pandemic Early Detection and Prevention Institute (hereinafter "institute") pursuant to Division 121 (commencing with Section 152000) of the Health and Safety Code. The remaining balance of the Revenue Stabilization Account may be transferred during the following fiscal year to the CPDI Fund for use for the purposes of the institute pursuant to Division 121 (commencing with Section 152000) of the Health and Safety Code.

(f) Transfers from the CPDI Fund to the Revenue Stabilization Account shall cease one year from the date of the cessation of the operation of the tax imposed pursuant to Section 17043.5, at which point the balance of the Revenue Stabilization Account shall be transferred into the CPDI

Fund for use by the institute pursuant to Division 121 (commencing with Section 152000) of the Health and Safety Code.

SECTION 10. Section 20069 of the Government Code is amended to read:

(a) "State service" means service rendered as an employee or officer (employed, appointed, or elected) of the state, the California Institute for Regenerative Medicine and the officers and employees of its governing body, *the California Pandemic Early Detection and Prevention Institute and the officers and employees of its governing body*, the university, a school employer, or a contracting agency, for compensation, and only while they are receiving compensation from that employer therefor, except as provided in Article 4 (commencing with Section 20990) of Chapter 11.

(b) "State service," solely for purposes of qualification for benefits and retirement allowances under this system, shall also include service rendered as an officer or employee of a county if the salary for the service constitutes compensation earnable by a member of this system under Section 20638.

(c) "State service," except for purposes of qualification for health or dental benefits, shall also include compensated service rendered by an officer, warrant officer, or a person of the enlisted ranks of the California National Guard who has elected to become a member pursuant to Section 20326 and who has not canceled their membership pursuant to Section 20327.

SECTION 11. Conformity with the State Constitution.

Section 24 is added to Article XVI of the California Constitution, to read:

SEC. 24.

(a) *The tax imposed by the California Pandemic Early Detection and Prevention Act (hereinafter, the "Act") and the revenue derived therefrom, including investment interest, shall not be considered General Fund revenues for purposes of Section 8 and its implementing statutes, and shall not be considered General Fund revenues, state revenues, or General Fund proceeds of taxes for purposes of subdivisions (a) and (b) of Section 8 and its implementing statutes.*

(b) *The tax imposed by the Act and the revenue derived therefrom, including investment interest, shall not be deemed General Fund proceeds of taxes or revenues that may be appropriated for purposes of Section 20 or 21 of this Article.*

Section 16 is added to Article XIII B of the California Constitution, to read:

SEC. 16. *"Appropriations subject to limitation" of each entity of government shall not include appropriations of revenues from the California Pandemic Early Detection and Prevention Fund created by the California Pandemic Early Detection and Prevention Act, or any other revenues deposited into any other funds pursuant to the act. No adjustment in the appropriations limit of*

any entity of government shall be required pursuant to Section 3 as a result of revenues being deposited in or appropriated from the California Pandemic Early Detection and Prevention Fund created by the California Pandemic Early Detection and Prevention Act or any other account pursuant to the act.

SECTION 12. Severability.

If any provision of this act, or part thereof, is for any reason held to be invalid or unconstitutional, the remaining provisions shall not be affected, but shall remain in full force and effect, and to this end the provisions of this act are severable.

SECTION 13. Effective Date.

The provisions of this act are written with the expectation that it will be enacted in November of 2022. In the event that it is approved by the voters at an election other than the one which shall occur during the 2022-23 fiscal year, the provisions of this act which refer to fiscal year 2023-24 shall be deemed to refer to the first year which begins after the effective date of this act and the provisions of this act which refer to other fiscal years shall refer to the year that is the same number of years after the first fiscal year as that year is in relationship to 2023-24.

SECTION 14. Conflicting Measures.

(a) In the event that this Initiative and another measure relating to metagenomic-sequencing-based pandemic detection shall appear on the same statewide election ballot, the provisions of the other measure or measures shall be deemed to conflict with this measure. In the event that this Initiative received a greater number of affirmative votes than a measure deemed to conflict with it, the provisions of this Initiative shall prevail in their entirety, and the other measure or measures shall be null and void.

(b) If this measure is approved by the voters but superseded by law by any other conflicting ballot measure approved by the voters at the same election, and the conflicting measure is later held invalid, this measure shall be self-executing and given the force of law.

SECTION 15. Liberal Construction.

This Initiative shall be liberally construed to effectuate its purposes.